

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Disposition of Claims

Claims 1-15 have been withdrawn. Claims 16-30 and 37 are canceled. Claim 31 is amended. No new matter has been added as the result of the amendment. Support for amended claim 31 can be found in the specification, for example, on page 9, lines 10-36. Upon entry of the amendment, claims 31-36 and 38-45 will be pending for examination on the merits.

II. Enablement Rejection

Claims 31-36 and 38-45 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not complying with the enablement requirement. Office Action, pp. 2-6. Specifically, the Office Action states that, although the claims are enabled for treating Meniere's disease by administering an IL-6 receptor antibody, they are not enabled for a method of treating inner ear disorder by administering an IL-6 antagonist. *Id.* Applicants respectfully traverse this ground of rejection, in light of the amendment to claim 31.

Claim 31, as amended, recites *a method for treating an inner ear disorder of a subject comprising administering an anti-interleukin-6 (anti-IL-6) receptor antibody to a subject in need thereof, wherein the anti-IL-6 receptor antibody binds to an IL-6 receptor, blocks signal transduction by IL-6 and inhibits the biological activity of IL-6.* The claimed method, therefore, does not encompass "every conceivable structure" as stated in the Office Action (pg. 3), but is directed to an antibody specific for an IL-6 receptor.

Moreover, the Chunthrapai reference, cited by the Office Action in support of its enablement rejection, actually contravenes the Office Action's assertion of non-enablement. On page 22, line 20, Chunthrapai states that "[o]ne can select antagonistic MAbs to a particular receptor by determining their abilities to inhibit bioactivities of the relevant ligand." According to Chunthrapai, therefore, one skilled in the art can readily identify appropriate

antibodies by determining their inhibitory characteristics. Indeed, as supported by the instant specification, there are known methods for assessing inhibitory activity of antagonists to signal transduction of IL-6. Specification, pg. 31, ll. 3-21 (describing the use of ^3H -thymidine and ^{125}I as indicators of IL-6 inhibition in cell cultures). Consequently, one skilled in the art would not face an undue burden in selecting appropriate antibodies to an IL-6 receptor, as claimed.

Accordingly, the claims, as amended, do not lack enablement for a method of treating inner ear disorder by administering, to a subject in need thereof, an antibody to an IL-6 receptor. Applicants, therefore, respectfully request that the enablement rejection of claims 31-36 and 38-45 be withdrawn.

III. Indefiniteness Rejection

Claims 31-36 and 38-45 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Office Action, pg. 6. Applicants respectfully traverse this ground of rejection.

Claim 31 has been described *supra*. The claim clearly recites the step of administering an anti-interleukin-6 receptor antibody. Moreover, the claim clearly indicates that the subject being administered the antibody is suffering from an inner ear disorder, as evidenced by the phrase “method of treating an inner ear disorder of a subject” (emphasis added). Furthermore, claiming a genus does not *per se* render a claim indefinite, as suggested by the Office Action. *Id.* Rather, one skilled in the art would understand that the claim is directed to a method of treating an inner ear disorder, which disorder encompasses multiple conditions, including Meniere’s disease. Accordingly, claim 31 is not vague or indefinite.

Applicants, therefore, respectfully request that the rejection of claims 31-36 and 38-45 be withdrawn.

IV. Prior Art Rejection – Anticipation

A. Kishimoto ‘510

Claims 31-36 and 38-39 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kishimoto et al. (US 5,888,510) (“Kishimoto ‘510”). Office Action, pp. 7-8. Applicants respectfully traverse this ground of rejection.

To anticipate a claim, a reference must teach each and every element of the claim. MPEP 2131. Applicants submit that Kishimoto ‘510 does not teach every element of the instant claims.

Claim 31 has been described *supra*. In contrast to the claimed method, Kishimoto ‘510 does not describe the step of administering, to a person in need of treatment for an inner ear disorder, an antibody to an IL-6 receptor. Although Kishimoto ‘510 describes an antibody to an IL-6 receptor, there is no teaching that the antibody can be used to treat an inner ear disorder. Indeed, Kishimoto ‘510 is directed to chronic rheumatoid arthritis. There is no mention of inner ear disorder, much less a step of administering an antibody to an IL-6 receptor to treat the inner ear disorder. Accordingly, Kishimoto ‘510 fails to anticipate claims 31-36 and 38-39.

Applicants, therefore, respectfully request that the rejection against claims 31-36 and 38-39 be withdrawn.

B. Kishimoto ‘268

Claims 31-36 and 38-43 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kishimoto et al. (EP 1074268) (“Kishimoto ‘268”). Office Action, pp. 9-10. Applicants respectfully traverse this ground of rejection.

To anticipate a claim, a reference must teach each and every element of the claim. MPEP 2131. Applicants submit that Kishimoto ‘268 does not teach every element of the instant claims.

Claim 31 has been described *supra*. In contrast to the claimed method, Kishimoto ‘268 does not describe the step of administering, to a person in need of treatment for an inner ear disorder, an antibody to an IL-6 receptor. Although Kishimoto ‘268 describes an antibody to an IL-6 receptor, there is no teaching that the antibody can be used to treat an inner ear

disorder. Indeed, Kishimoto ‘268 is directed to inflammatory bowel disease, including Crohn’s disease and ulcerative colitis. There is no mention of inner ear disorder, much less administering an antibody to an IL-6 receptor for treating the inner ear disorder. Accordingly, Kishimoto ‘268 fails to anticipate claims 31-36 and 38-43.

Applicants, therefore, respectfully request that the rejection against claims 31-36 and 38-43 be withdrawn.

V. Prior Art Rejection – Obviousness

Claims 31-45 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kishimoto et al. (EP 1074268) (“Kishimoto ‘268”) in view of Queen et al. (US 5,530,101) (“Queen”). Office Action, pp. 11-12. Applicants respectfully traverse this ground of rejection.

Kishimoto ‘268 has been described *supra*. Applicants submit that Queen fails to remedy the deficiencies of Kishimoto ‘268.

Queen is directed to humanized immunoglobulins having one or more complementary determining regions and methods of making thereof. Queen, abstract; col. 2, ln. 35 to col. 3, ln. 58.; and col. 10, ln. 55 to col. 20, ln. 33. Queen, however, does not describe or suggest *a method for treating an inner ear disorder of a subject comprising administering an anti-interleukin-6 (anti-IL-6) receptor antibody to a subject in need thereof, wherein the anti-IL-6 receptor antibody binds to an IL-6 receptor, blocks signal transduction by IL-6 and inhibits the biological activity of IL-6*, as claimed. Indeed Queen does not even mention an antibody to an IL-6 receptor. Moreover, Queen does not teach or fairly suggest administering any antibody for treating an inner ear disorder.

Lacking teaching or a suggestion to treat an inner ear disorder by administering an anti-IL-6 receptor antibody, Kishimoto ‘268 and Queen, individually or in combination, fail to render the instant claims obvious.

Applicants, therefore, respectfully request that the rejection of claims 31-36 and 38-45 be withdrawn.

VI. Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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